

I. The Election/Restriction Requirement Is Improper Based On The MPEP §803

The Action has not met its burden of providing reasons and/or examples to support its conclusion that the compound claims belonging to Groups I and III are independent and distinct inventions. MPEP § 803.01. In this regard, the only "explanation" provided by the Action is the conclusory statement that "[i]nventions I and III are related as independent and distinct products which differ materially in structure and composition" (Action at 6).

Moreover, although Formulas I and II represented by Groups I and II, respectively, differ in structure in certain respects, the Action has not provided an explanation detailing the reasons for alleging that the compounds are so different that it would be a burden to examine the compounds of Groups I and III as part of the same invention. For example, the generic structure that is the subject of Group III, *i.e.*, Formula II, is a species of the generic structure that is the subject of Group I, *i.e.*, Formula I. In other words, Formula II is Formula I wherein R¹ is (a) and X¹ is -C(O)-. Applicants do not understand how such relationship would make examination of the two formulas burdensome. Accordingly, reconsideration and withdrawal of the election/restriction requirement is requested respectfully.

II. The Species Election/Restriction Requirement Is Improper Based On The MPEP §803.02 And Relevant Case Law

Applicants submit respectfully that the species election/restriction is improper for dividing Applicants' Markush claim in contravention to the requirements of MPEP §803.02 and the case law.

A. MPEP §803.02 Considerations

MPEP §803.02 provides that there is no basis for an Election/Restriction of a Markush claimed invention where two factors are met, *i.e.*,

... compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature

Applicants' claimed invention meets the aforesaid factors. Regarding the first factor, that the compounds share a common utility, the compounds of each of Groups I-IV are useful as inhibitors of cathepsins and, thus, are useful in treating diseases associated with activity of cathepsins.

Regarding the second factor, the compounds of the claimed invention all share a substantial structural feature, *i.e.*, the structure represented by Formula I.

Moreover, it is well established that the Action must provide reasons and/or examples to support conclusions when issuing a restriction requirement. MPEP § 803. The Action, however, has not met this requirement. The Action has based its conclusion on a presumption, the truth of which has not been shown. In this regard, the Action presumes that the constituents of the Markush group substituents are so dissimilar that the chemical compounds within the scope of the defined substituents do not function similarly (Action at 9). The Action, however, provides no evidence or scientific reasoning to support its "presumption." Accordingly, Applicants respectfully submit that the election/restriction requirement is improper on its face for failing to comply with the requirements set forth in the MPEP.

B. Case Law Considerations

As detailed below, well-settled case law such as, for example, *In re Harnisch*, 206 U.S.P.Q. 300 (CCPA 1980), supports Applicants' position that the present restriction requirement is improper because, as stated above, the Action has provided *no* evidence or technical reasoning to support its apparent conclusion that the compounds within the Markush groups do *not* share a common utility and do *not* share a substantial structural feature.

In re Harnisch, 206 U.S.P.Q. 300 (CCPA 1980)

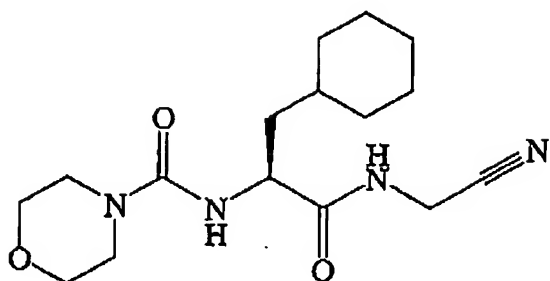
In *re Harnisch*, 206 U.S.P.Q. 300 (CCPA 1980), the court found that an invention claimed in a Markush type claim was proper for compounds having a common utility and “a *single structural similarity*” (emphasis added). In particular, in agreeing with its earlier decisions, the court stated that a Markush group was proper where there is a

grouping of compounds having the *same nuclei but side chains wherein there was a wide variation ... and had a community of properties justifying their grouping ...* was not repugnant to principles of scientific classification.

In re Harnisch, 206 U.S.P.Q. at 305 (emphasis added). The Court held that, when such criteria exist, there is unity of invention within the claimed Markush group. *Id.* Applicants’ claimed invention meets the standard of *In re Harnisch* as it indeed has the requisite single structural similarity (*i.e.*, the substantial structural feature from MPEP §803.02) and shares a common utility, as noted above. Therefore, there is no proper basis for the present election/restriction.

Provisional Election

Although Applicants submit respectfully that the imposed election/restriction is improper, in an attempt to advance the prosecution of this application to allowance, Applicants provisionally elect Group I. Further, in response to the requirement to elect a species within the elected group as a starting point for a prior art search, Applicants elect the compound N-(1S-Cyanomethylcarbamoyl-2-cyclohexylethyl)morpholine-4-carboxamide. This compound is represented by the structure:



, and is the subject of Example 5 in

Applicants' specification (page 69).

Applicants submit that once the compounds of the present invention are found to be novel, then the other Groups defined by the Examiner that contain any compositions of matter containing those compounds should also be found to be novel and rejoined. Further, Applicants reserve the right to pursue any compounds that remain after prosecution of the instant patent application in a future divisional patent application.

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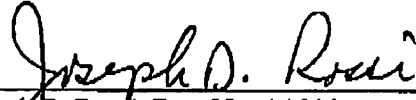
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Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Applicants respectfully submit that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested.

The Commissioner is hereby authorized to charge the fee required and any additional fees that may be needed to Deposit Account No. 18-1982 in the name of Aventis Pharmaceuticals Inc.

Respectfully submitted,



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